JUN - 8 2009

Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: k090737.

Submitter:

Bio-Rad Laboratories, Inc., Clinical Systems Division, 4000 Alfred Nobel Drive, Hercules, California 94547

Phone: (510) 741-6114; Fax: (510) 741-3954

Contact Person:

Jolene Bartilson, Regulatory Affairs Representative

Device Name:

Hemoglobin Capillary Collection System (HCCS)

Classification Name:

Blood specimen collection device, JKA

Assay, Glycosylated hemoglobin, LCP

Predicate Devices:

VARIANT™ II Hemoglobin A1c Program, Bio-Rad Laboratories, Inc., K070452 - Wash/Diluent Solution

D-10™ Hemoglobin A1c Program, Bio-Rad Laboratories, Inc., K031043 - Wash/Diluent Solution

Intended Use:

The Hemoglobin Capillary Collection System (HCCS) is intended for the collection of human whole blood for the percent determination of hemoglobin A1c using Bio-Rad HPLC methods.

For *in vitro* diagnostic use.

Indications For Use:

The measurement of percent hemoglobin A1c is effective in monitoring long-term glucose control in individuals with diabetes mellitus.

Description of the Device:

Each Hemoglobin Capillary Collection System (HCCS) contains a combination of the following components (quantity is dependent upon kit size):

1. Sample Preparation Vials: clear microvials with blue pierceable caps, each contains 1.5 mL of the HCCS reagent.

2. Capillaries: plastic capillaries (5 µL) in a dispenser.

3. Capillary Holder: holder for manipulating the capillaries.

4. Labels: to label prepared samples.

The HCCS provides the necessary materials for a professional user to collect and prepare whole blood samples (capillary or venous blood) for analysis with the VARIANT™ II Hemoglobin A1c Program run on the VARIANT™ II Hemoglobin Testing System or the D-10™ Hemoglobin A1c Program run on the D-10™ Hemoglobin Testing System.

Technical Characteristics Compared to the Predicates:

The Hemoglobin Capillary Collection System (HCCS) reagent is intended to dilute whole blood samples in the same way that the predicate Wash/Diluent Solutions of the VARIANT™ II Hemoglobin A1c Program and D-10™ Hemoglobin A1c Program are used to dilute whole blood samples; in preparation for the percent determination of hemoglobin A1c in human whole blood using ion-exchange high-performance liquid chromatography (HPLC). The similarities and differences between the HCCS and the predicates are summarized in the following table:

Characteristic	**New Device: Hemoglobin Capillary Collection System (HCCS)**	**Predicate Device: VARIANT™ II HbA1c Program, Wash/Diluent Solution (K070452)**	**Predicate Device: D-10™ HbA1c Program, Wash/Diluent Solution (K031043)**
Intended Use	The Hemoglobin Capillary Collection System (HCCS) is intended for the collection of human whole blood for the percent determination of hemoglobin A1c using Bio-Rad HPLC methods. For	The Bio-Rad VARIANT II Hemoglobin A1c Program is intended for the percent determination of hemoglobin A1c in human whole blood using ion-exchange high performance liquid chromatography	The Bio-Rad D-10 Hemoglobin A1c Program is intended for the percent determination of hemoglobin A1c in human whole blood using ion-exchange high-performance liquid chromatography (HPLC). The Bio-Rad

	in vitro diagnostic use.	(HPLC). The Bio-Rad VARIANT II Hemoglobin A1c Program is intended for Professional Use Only.	D-10 Hemoglobin A1c Program is intended for Professional Use Only.
Indications For Use	Measurement of percent hemoglobin A1c is effective in monitoring long-term glucose control in individuals with diabetes mellitus.	Measurement of percent hemoglobin A1c is effective in monitoring long-term glucose control in individuals with diabetes mellitus.	Measurement of percent hemoglobin A1c is effective in monitoring long-term glucose control in individuals with diabetes mellitus.
Formulation	Aqueous solution of EDTA and potassium cyanide.	Deionized water with <0.05% sodium azide as a preservative.	Deionized water with <0.05% sodium azide as a preservative.
Sample Type	Capillary or venous blood from plastic capillary.	Venous whole blood sample collected in an EDTA vacuum collection tube.	Venous whole blood sample collected in an EDTA vacuum collection tube.
Purpose of Reagent	Sample dilution for hemoglobin A1c analysis using Bio-Rad HPLC methods.	Sample dilution for hemoglobin A1c analysis using Bio-Rad HPLC method.	Sample dilution for hemoglobin A1c analysis using Bio-Rad HPLC method.
Timing of Dilution Step	Sample dilution at time of sample collection. No further preparation is required; the VARIANT II Hemoglobin Testing System and D-10 Hemoglobin Testing System do not perform dilution on samples withdrawn from sample vials.	Dilution with the Wash/Diluent Solution is performed automatically by the VARIANT II Hemoglobin Testing System at time of analysis; when vacuum collection tubes are used.	Dilution with the Wash/Diluent Solution is performed automatically by the D-10 Hemoglobin Testing System at time of analysis; when vacuum collection tubes are used.
Stability of Sample	Prepared samples can be passed on for analysis or shipped to another	Whole blood specimens may be stored up to 7 days at 2 to 8 °C.	Whole blood specimens may be stored up to 7 days at 2 to 8 °C or 3 days at

	location. Samples are stable for: 4 days at 42 °C, 2 weeks at 15 to 30 °C, or 4 weeks at 2 to 8 °C.		room temperature (15 to 30 °C).

Testing to Establish Substantial Equivalence:

Method Comparison:

A method comparison study was conducted at an external site to determine if there is a significant difference in the hemoglobin A1c values of capillary samples collected and prepared with the Hemoglobin Capillary Collection System (HCCS) versus the values obtained from the corresponding venous whole blood samples when analyzed with the VARIANT™ II Hemoglobin A1c Program on the VARIANT™ II Hemoglobin Testing System and with the D-10™ Hemoglobin A1c Program on the D-10™ Hemoglobin Testing System. One HCCS capillary sample and one venous EDTA primary tube sample were collected from each patient; the samples were then analyzed with the VARIANT™ II Hemoglobin A1c Program or the D-10™ Hemoglobin A1c Program. The results of the study are summarized in the tables below:

HCCS Comparison Study on the VARIANT™ II Hemoglobin A1c Program

Method	Sample Value Range	n	R^2	Slope	Intercept
VII HbA1c Program	4.9 to 14.6 %HbA1c	40	0.9977	1.0221	-0.0701

HCCS Comparison Study on the D-10™ Hemoglobin A1c Program

Method	Sample Value Range	n	R^2	Slope	Intercept
D-10 HbA1c Program	4.8 to 14.3 %HbA1c	40	0.9977	1.0221	-0.0685

Conclusion:

The results of the method comparison study and performance evaluation studies of the Hemoglobin Capillary Collection System (HCCS) show that there is no significant difference in the hemoglobin A1c values for whole blood samples prepared with the HCCS versus whole blood samples diluted with the predicate Wash/Diluent Solutions of the VARIANT II Hemoglobin A1c Program and D-10 Hemoglobin A1c Program. Therefore, we trust that the information provided in this 510(k) Submission will support a decision of substantial equivalence of the Hemoglobin Capillary Collection System (HCCS).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Bio-Rad Laboratories, Inc
c/o Ms. Jolene Bartilson
4000 Alfred Nobel Dr
Hercules, CA 94547

JUN - 3 2009

Re: k090737
Trade/Device Name: Hemoglobin Capillary Collection System
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated Hemoglobin Assay
Regulatory Class: Class II
Product Code: LCP and JKA
Dated: March 19, 2009
Received: March 20, 2009

Dear Ms. Bartilson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Indication for Use

510(k) Number (if known): K090737

Device Name: Hemoglobin Capillary Collection System (HCCS)

Indication For Use:

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For in vitro diagnostic use.

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Prescription Use X (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K090737